

August 26, 2002

Adrienne Kiley  
Technical Contact  
Propylene Carbonate/t-Butyl Alcohol  
High Production Volume Committee  
1250 Connecticut Avenue, N.W. Suite 700  
Washington, D.C. 20036

Dear Ms. Kiley:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Propylene Carbonate posted on the ChemRTK HPV Challenge Program Web site on May 2, 2002. I commend The Propylene Carbonate/t-Butyl Alcohol HPV Committee for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The Propylene Carbonate/t-Butyl Alcohol HPV Committee advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: W. Sanders  
A. Abramson  
C. Auer  
M. E. Weber

## **EPA Comments on Chemical RTK HPV Challenge Submission: Propylene Carbonate**

### **SUMMARY OF EPA COMMENTS**

The Sponsor, Propylene Carbonate/t-Butyl Alcohol HPV Committee, submitted a test plan and robust summaries to EPA for propylene carbonate (CAS No. 108-32-7) dated April 10, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on May 2, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. EPA agrees with the submitter's proposal to conduct a stability in water test and to estimate environmental transport/distribution (fugacity). With the exception of biodegradation, all other appropriate SIDS-level tests/estimations have been performed.
2. Health Effects. All appropriate SIDS-level tests have been performed. The submitter needs to address deficiencies in the robust summaries.
3. Ecological Effects. Acceptable data are available on the analog butylene carbonate to address the fish and invertebrate endpoints. EPA agrees with the submitter's proposal to conduct an algal toxicity test.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### **EPA COMMENTS ON THE PROPYLENE CARBONATE CHALLENGE SUBMISSION**

#### **Test Plan**

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

With the exception of biodegradation, the submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program. However, EPA recommends the use of a Level III fugacity model instead of Level I.

#### *Biodegradation.*

EPA disagrees with the sponsor's assertion that adequate biodegradation data exist and that no further testing is needed, pending clarification of the submitted data. The robust summary for the biodegradation endpoint is based on an English abstract of a study published in German. The submitted data suggest that the substance is readily biodegradable, but the sponsor needs to provide experimental details to allow EPA to evaluate its claims.

*Fugacity.* The sponsor proposes to estimate the fugacity of these chemicals using a Level I EQC model. Although EPA had previously recommended the use of EQC Level I, this model is somewhat limited. EPA now recommends a level III analysis, which is more rigorous. The EQC and EPIWIN Level III models are acceptable.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for all health endpoints for the purposes of the HPV Challenge Program. However, the submitter needs to address deficiencies in the robust summaries.

*Reproductive/Developmental Toxicity.* EPA agrees with the submitter to use data from an adequate 90-day repeated-dose toxicity study with examination of the reproductive organs showing no effects and an adequate developmental study to address the reproductive/developmental toxicity endpoint.

Ecotoxicity (fish, invertebrates, and algae). The submitter proposes to use data on the structurally similar butylene carbonate to address the fish and aquatic invertebrate endpoints for propylene carbonate. EPA agrees that butylene carbonate is an acceptable analog to address these endpoints and with the submitter's proposal to conduct an algal toxicity test. EPA notes that the algal medium preparation in this test should be followed according to OECD TG 201.

### **Specific Comments on the Robust Summaries**

Health Effects.

For all robust summaries, the submitter needs to provide the purity of the test material. Also, in a number of the robust summaries the submitter did not clearly indicate the NOAEL (NOEL) and/or the LOAEL.

### **Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.